Exhibit 4

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA

PETER POE, et al., *Plaintiffs*, v. GENTNER DRUMMOND, et al., *Defendants*.	Case No. 23-CV-00177-JFH-SH

REPLY DECLARATION OF
ARMAND H. MATHENY ANTOMMARIA, MD, PhD, FAAP, HEC-C

I, Armand H. Matheny Antommaria, hereby declare and state as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. I have actual knowledge of the matters stated herein.

3. In preparing this declaration, I reviewed the Defendants' Response to Plaintiffs' Motion for Preliminary Injunction (hereafter Response) and the expert declarations of James Cantor, PhD, Michael K. Laidlaw, MD, Angela C.E. Thompson, MD, MPH, FACOG, and Curtis E. Harris, MS, MD, JD, filed by the Defendants in this case.[1]

4. In this reply declaration, I show that these experts inaccurately characterize the role of patients' symptoms in diagnosis; mischaracterize gender-affirming medical care as experimental; inaccurately represent the levels of evidence provided by systematic reviews, randomized controlled trials (RCT), and observational studies; misrepresent the level of evidence

[1] I cite the Response by page number and the expert declarations by paragraph number unless otherwise noted.

generally available for medical decision making; inaccurately represent European policies on gender-affirming medical care; inaccurately portray the informed consent process; and misrepresent parents' and adolescents' medical decision-making capacity. Further, my review of the Response and the Defendants' experts' declarations does not provide me reason to change my opinion that there is no sound medical or ethical basis to prohibit healthcare professionals from providing gender-affirming medical care to minors.

ROLE OF SYMPTOMS IN MEDICAL DIAGNOSIS

5. The Defendants and their experts improperly seek to impugn the diagnosis of gender dysphoria by contending that it does not have a locus in the physical body[2] and that the diagnosis is subjective rather than objective. [3]

6. Gender dysphoria is a psychiatric diagnosis contained in the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders*.[4] As such, its "physical" location is the brain. This does not make the diagnosis any less real or its potential complications any less severe.

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[2] Cantor 110, Laidlaw 16-23, and Thompson 5-6, 8, 25, 122, 140.

[3] Response 24, Cantor 59, 106, 109, 277, 281-282, Laidlaw 16-23, 50-51, 79, 222, Thompson 123, and Harris 26, 30.

[4] American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed, Text Revision. American Psychiatric Publishing; 2022. Dr. Cantor incorrectly distinguishes "medical" and psychiatric diagnoses based on whether they identify the cause of a patient's symptoms or label the symptoms themselves (278, 281-282). On the contrary, there are medical diagnoses that are symptoms and medical diagnoses whose cause is unknown. As a pediatric hospitalist, I treat patients for "abdominal or pelvic pain," International Classification of Diseases for Mortality and Morbidity Statistics, 11th Revision code MD81, without ever knowing the cause of their symptoms. There are also diseases that represent a constellation of signs and symptoms whose cause is unknown. I would provide the example of Kawasaki disease. See McCrindle BW, Rowley AH, Newburger JW, et al. Diagnosis, treatment, and long-term management of Kawasaki disease: A scientific statement for health professionals from the American Heart Association. *Circulation*. 2017;135(17):e927-e999. Dr. Thompson provides the example of polycystic ovarian syndrome (69).

7. Contrary to the Defendants' experts' claims, the fact that the diagnosis of gender dysphoria relies on patients' reports of their symptoms and is not confirmed by laboratory or radiographic testing does not undermine its validity. In addition to the fact that most mental health conditions have this characteristic, the diagnosis of some non-mental health conditions also relies on patients' reports of their symptoms and are unable to be confirmed by laboratory or radiographic testing. The diagnosis of migraine headaches, for example, depends on individuals' report of the number, duration, and characteristics of their headaches. These characteristics include the headaches' location, quality, intensity, and aggravating factors as well as the presence of nausea and/or vomiting, and light and sound sensitivity.[5] Like gender dysphoria, there are no confirmatory laboratory or radiographic studies for the diagnosis of migraine headaches. Radiographic studies and electroencephalograms (EEG) are only used if the history and physical examination suggest that the headache is caused by another condition, e.g., meningitis or subarachnoid hemorrhage.[6] Clinical trials of migraine treatments, including randomized, double-bind/masked, placebo-controlled trails, rely on participants' daily headache diaries.[7]

TERMINOLOGY

Experimental

8. The Defendants' experts characterize gender-affirming medical care as

[5] Headache Classification Committee of the International Headache Society (IHS). The international classification of headache disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1-211.
[6] Steiner TJ, Jensen R, Katsarava Z, et al. Aids to management of headache disorders in primary care, 2nd edition. *J Headache Pain*. 2019;20(1):57.
[7] Powers SW, Coffey CS, Chamberlin LA, et al. Trial of amitriptyline, topiramate, and placebo for pediatric migraine. *N Engl J Med*. 2017;376(2):115-124; Ailani J, Lipton RB, Goadsby PJ, et al. Atogepant for the preventive treatment of migraine. *N Engl J Med*. 2021;385(8):695-706.

experimental.[8] To the extent that they provide definitions of this term, these definitions are erroneous. Dr. Cantor, for example, contends, "A treatment would continue to be experimental until the demonstration of (1) reliable, clinically meaningful improvement and (2) the reliable estimation of safety risks in randomized, controlled trials (RCTs) or research of equivalent evidence (166)."[9] Dr. Cantor does not provide any references to support his claim. If this definition were correct, which it is not, many widely accepted medical treatments would be classified as experimental, including ones that the Defendants' experts accept are not experimental. For example, the use of gonadotropin-releasing hormone (GnRH) analogs to treat central precocious puberty is based on observational studies.[10] Dr. Cantor's definition would classify this use as experimental because it is not based on RCT. The use of GnRH analogs for this indication is not, however, experimental as demonstrated by its approval by the United States (US) Food and Drug Administration (FDA), widespread use in clinical practice, and characterization by the Defendants' own expert.[11]

9. Dr. Thompson's use of the term "experimental" also demonstrates the falsity of Dr. Cantor's definition. While Dr. Thompson asserts, "In both female and male children, fertility-sparing procedures prior to full pubertal development are nascent and considered to be

[8] Response 17, 24, Cantor 166, 168-172, 176-177, 285, 287, Laidlaw 58, 76, 118-119, 145, and Thompson 4.
[9] See also Cantor "Missing from [Dr. Antommaria's] analysis is the *scientific* sense [of experimental]: untested by experimental research (285. See also 287)" and Laidlaw "The use of [gonadotropin-releasing hormone] analogue medication for this purpose in adolescents is experimental as there have been no randomized controlled trials for this specific use case (76)."
[10] HIGHLIGHTS OF PRESCRIBING INFORMATION. May 2017. Accessed June 29, 2023. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020263s042lbl.pdf; Mul D, Hughes IA. The use of GnRH agonists in precocious puberty. *Eur J Endocrinol*. 2008;159(Suppl 1):S3-8; Carel JC, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics*. 2009;123(4):e752-62.
[11] Liadlaw 73-74.

experimental (88)," she implicitly endorses the American Society for Reproductive Medicine's removal of the label "experimental" from ovarian tissue cryopreservation for individuals who were assigned female at birth and have completed puberty.[12] The evidence justifying this decision is achieving 130 live births using this method.[13] Many of the reports of successful live births appeared in case reports[14] and were not the result of RCT. The difference between non-experimental and experimental, therefore, cannot depend on the existence of RCT. I will also note that the pregnancy and live birth rates of individual centers offering ovarian tissue cryopreservation at that time were, at most, 29-33% and 23-25% respectively.

Off-Label

10. The Response (6, 8) and Dr. Laidlaw (76, 78, 119, 140, 201) also emphasize that GnRH analogs, testosterone, estrogen, and spironolactone are not approved by the FDA for their use in gender-affirming medical care or, in other words, that they are used off-label. As I noted in my initial declaration, the fact that a medication is not approved by the FDA for a particular indication does not necessarily mean that this use is experimental or lacks evidence.[15] Off-label use is common in pediatrics.[16]

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[12] Practice Committee of the American Society for Reproductive Medicine. Fertility preservation in patients undergoing gonadotoxic therapy or gonadectomy: A Committee opinion. *Fertil Steril*. 2019;112(6):1022-1033.
[13] Donnez J, Dolmans MM. Fertility preservation in women. *N Engl J Med*. 2017;377(17):1657-1665.
[14] Donnez J, Dolmans MM, Pellicer A, et al. Fertility preservation for age-related fertility decline. *Lancet*. 2015;385(9967):506-507.
[15] Frattarelli DA, Galinkin JL, Green TP, et al. Off-label use of drugs in children. *Pediatrics*. 2014;133(3):563-567; Wittich CM, Burkle CM, Lanier WL. Ten common questions (and their answers) about off-label drug use. *Mayo Clin Proc*. 2012;87(10):982-990.
[16] Yackey K, Stukus K, Cohen D, Kline D, Zhao S, Stanley R. Off-label medication prescribing patterns in pediatrics: An update. *Hosp Pediatr*. 2019;9(3):186-193; Maltz LA, Klugman D, Spaeder MC, Wessel DL. Off-label drug use in a single-center pediatric cardiac intensive care unit. *World J Pediatr Congenit Heart Surg*. 2013;4(3):262-266.

CLINICAL PRACTICE GUIDELINES

Development Process

11. Dr. Cantor states that individuals who provide care to patients with gender dysphoria have conflicts of interest (11. See also 175, 292, 302). On the contrary, they do not have conflicts of interest in the relevant sense. If the treatment for gender dysphoria were hypothetically to change, providers would continue to be compensated for providing this new treatment or treating patients with other conditions. It is unclear who Dr. Cantor expects to write clinical practice guidelines if not experts in the relevant fields.

12. Professional organizations screen potential authors of clinical practice guidelines for real conflicts of interest. At the time the Endocrine Society published its current clinical practice guideline on gender-affirming medical care, it defined conflict of interest as follows: "remuneration in any amount from commercial interest(s) in the form of grants; research support; consulting fees; salary; ownership interest (eg, stocks, stock options [excluding diversified mutual funds]); honoraria or other payments for participation in speakers' bureaus, advisory boards, or boards of directors; or other financial benefits (square brackets in original)."[17] The guideline itself lists the authors' financial disclosures.[18]

13. Contrary to Dr. Laidlaw's assertion (192, 196, 199), membership in or leadership of another professional society also does not itself constitute a relevant conflict of interest. It is not uncommon for health care professionals to be members of multiple professional societies. Dr. Cantor, for example, was a member of eight professional societies at the same time

[17] Endocrine Society. Clinical practice guideline methodology. Accessed June 29, 2023. Available at https://web.archive.org/web/20170627174844/http://www.endocrine.org/education-and-practice-management/clinical-practice-guidelines/methodology.

[18] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

(Appendix 1, page 28) and concurrently held offices in more than one society (Appendix 1, page 27).

Quality of Evidence

14. Dr. Cantor emphasizes the Pyramid of Evidence, systematic reviews, and randomized controlled trails (5, 40-43, 74-76, 79-88). In contrast to the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) approach, the pyramid is a heuristic device used to describe the quality of the evidence and is not an actual method for grading the quality of evidence. The GRADE approach uses four categories to characterize the quality of the evidence: "high," "medium," "low," and "very low." While RCT are initially assigned to the high category and observational studies to the low, studies may be reassigned to lower or higher categories based on other factors in their design and execution. A RCT might, therefore, provide very-low quality evidence and an observational study high.[19]

15. Dr. Cantor focuses a significant amount of his declaration on systematic reviews. The Cochrane Collaboration defines systematic reviews as follows: "A systematic review attempts to identify, appraise and synthesize all the empirical evidence that meets pre-specified eligibility criteria to answer a specific research question. Researchers conducting systematic reviews use explicit, systematic methods that are selected with a view aimed at minimizing bias, to produce more reliable findings to inform decision making."[20] Systematic review do not generate new evidence, they summarize existing evidence. Meta-analyses, which are sometimes performed in conjunction with systematic reviews, combine the results of individual studies into

[19] Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.
[20] Cochrane Library. About Cochrane Reviews. Accessed June 30, 2023. Available at https://www.cochranelibrary.com/about/about-cochrane-reviews.

an overall statistic that did not previously exist.

16. A key characteristic of systematic reviews is grading the quality of the evidence. Dr. Cantor cites the meta-epidemiological study by Helene Moustgaard and her colleagues in support of his claim that blinding/masking makes little or no difference to the quality of the evidence in practice (51). In their article, Dr. Moustgaard and her colleagues, however, state, "Meta-epidemiological studies are observational and so estimated effects of trial characteristics could be confounded" and "At this stage, replication of this study is suggested and blinding should remain a methodological safeguard in trials."[21] Dr. Cantor's interpretation of this article therefore contradicts its authors' own conclusions and recommendations.

17. The Response and the Defendants' experts emphasize the quality of the evidence currently available regarding gender-affirming medical care.[22] They fail to acknowledge, however, that most systematic reviews find low or very low-quality evidence. Padhraig S. Fleming and colleagues conducted a review of systematic reviews published on the Cochrane Database of Systematic Reviews between January 1, 2013, and June 30, 2014. They focused on those that incorporated the GRADE approach and examined the quality of evidence for the first listed primary outcome. Of the 608 reviews, 82 (13.5%) reported high, 197 (30.8%) moderate, 193 (31.7%) low, and 126 (24%) very low-quality evidence.[23] In a subsequent study, a related

[21] Moustgaard H, Clayton GL, Jones HE, et al. Impact of blinding on estimated treatment effects in randomized clinical trials: Meta-epidemiological study. *BMJ*. 2020;368:l6802.
[22] Response 11, Cantor 299, Thompson 7, and Harris 28.
[23] Fleming PS, Koletsi D, Ioannidis JP, Pandis N. High quality of the evidence for medical and other health-related interventions was uncommon in Cochrane systematic reviews. *J Clin Epidemiol*. 2016;78:34-42. See also Howick J, Koletsi D, Ioannidis JPA, et al. Most healthcare interventions tested in Cochrane Reviews are not effective according to high quality evidence: A systematic review and meta-analysis. *J Clin Epidemiol*. 2022;148:160-169 that found only 10.1% of interventions (158 of 1,567) had high quality evidence supporting their benefits.

group of authors found that updated reviews did not consistently demonstrate an improvement in the quality of the evidence.[24]

18. The Defendants' experts also fail to adequately address the ethical and logistical barriers to conducting the type of RCT that they intimate is needed. Dr. Cantor, for example, asserts "When a 'no treatment control group' is untenable, RCTs use an 'active comparator' group instead (page 23)." In support of this claim, Dr. Cantor cites the evidence reviews conducted by England's National Institute for Health and Care Excellence. These reviews simply state, "There may also be ethical issues with a 'no treatment arm' in comparative trials of gender-affirming hormones, where there may be poor mental health outcomes if treatment is withheld. However, the use of an active comparator such as close psychological support may reduce ethical concerns in future trials."[25] These two sentences neither provide a detailed study protocol nor demonstrate that the reduction in ethical concerns will be sufficient to make such trials ethical.[26]

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[24] Howick J, Koletsi D, Pandis N, et al. The quality of evidence for medical interventions does not improve or worsen: a metaepidemiological study of Cochrane reviews. *J Clin Epidemiol*. 2020;126:154-159.

[25] NICE. Evidence review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria. October 2020. Page 40. Accessed June 29, 2023. Available at https://cass.independent-review.uk/wp-content/uploads/2022/09/20220726_Evidence-review_GnRH-analogues_For-upload_Final.pdf; NICE. Evidence review; Gender-affirming hormones for children and adolescents with gender dysphoria. October 2020. Accessed June 29, 2023. Available at https://cass.independent-review.uk/wp-content/uploads/2022/09/20220726_Evidence-review_Gender-affirming-hormones_For-upload_Final.pdf.

[26] Alternative study designs or methods of statistical analysis may ethically address some of the limitations of observational studies. In their study of the effects of gender-affirming hormone treatment, Diane Chen and colleagues used linear latent growth curve modeling to examine how initial levels and rates of change in appearance congruence correlated with psychosocial functioning. They found increases in appearance congruence were associated with decreases in depression and anxiety and increases in positive affect and life satisfaction. Chen D, Berona J, Chan YM, et al. Psychosocial functioning in transgender youth after 2 years of hormones. *N Engl J Med*. Jan 19 2023;388(3):240-250. These association would not be expected if improvements

19. As discussed below, the National Health Service England has restricted the use of GnRH analogues to a formal research protocol,[27] but has not announced the specific protocol(s). The Swedish National Board of Health and Welfare (NBHW) has explicitly stated that the research context does not necessarily imply the use of RCT.[28]

20. Systematic reviews have many critical roles including identifying future research priorities.[29] In contrast to clinical practice guidelines, systematic reviews do not, however, make treatment recommendations.[30] The Response demonstrates a misunderstanding of this distinction when it states, "For various reasons, including its overruling of systematic review results based on the '*lowest* level of evidence in science,' the [World Professional Association for Transgender Health (WPATH)] guidelines 'cannot be called evidence-based guidelines under any accepted meaning of that term (4, italics in original).'" WPATH does not "overrule" the systematic reviews' evaluation of the quality of the evidence; WPATH does not assert that the evidence for gender-affirming medical care for adolescents is high or moderate quality. And because systemic reviews do not make treatment recommendations, in making treatment

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in functioning were the result of concurrent psychotherapy that would not affect appearance congruence. Contrast Cantor 199.

[27] NHS England. Consultation report for the interim service specification for specialist gender incongruence services for children and young people. June 9, 2023. Page 47. Accessed June 29, 2023. Available at https://www.england.nhs.uk/wp-content/uploads/2023/06/Consultation-report-on-interim-service-specification-for-Specialist-Gender-Incongruence-Services-for-Children-.pdf.

[28] Socialstyrelsen. Care of children and adolescents with gender dysphoria: Summary. Accessed June 29, 2023. Available at https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-3-7799.pdf. See also, The Cass Review. Independent review of gender identity services for children and young people: Interim report. February 2020. Recommendation 8, Page 22. Accessed June 29, 2023. Available at https://cass.independent-review.uk/publications/interim-report/.

[29] Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. *BMJ*. 2021;372:n71.

[30] National Heart, Lung, and Blood Institute. About systematic evidence reviews and clinical practice guidelines. Accessed June 30, 2023. Available at https://www.nhlbi.nih.gov/node/80397.

recommendations, WPATH cannot "overrule" systematic reviews.

Strength of Recommendations

21. The quality of the evidence, as defined by a grading system, is only one factor considered in clinical practice guidelines when making recommendations and rating their strength. The other factors are the balance between the desirable and undesirable outcomes, the confidence in values and preferences and variability, and resource use.[31] Dr. Cantor's purported scientific expertise (9-15) is not sufficient for developing and rating treatment recommendations; clinical expertise is necessary to understand the potential benefits, risks, and patients' values and preferences; and to balance the potential benefits and risks from the patients' perspective.

22. My initial declaration demonstrates that the recommendations of many clinical practice guidelines are based on low or very low-quality evidence.[32] If Oklahoma were to ban all medical treatments based on these levels of evidence, rather than just medical treatments for gender dysphoria, it would have a devastating effect on the practice of medicine and on patients.

23. Dr. Laidlaw's contention that "Dr. Antommaria fails to recognize that the purpose and use of hormones and surgeries in [gender-affirming treatment] is fundamentally different than cardiopulmonary resuscitation for life support (201)" entirely mises the point. I cited the American Heart Association's guideline for Pediatric Basic and Advanced Life Support in my

[31] Andrews JC, Schunemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66(7):726-735.

[32] There are not broad studies of the quality of the evidence cited in clinical practice guidelines like the studies of the quality of the evidence reported in systematic reviews that are cited in footnote 27. Jonathan M. Hazelhurst and colleagues, however, did examine the guidelines from major endocrine organizations and found that only 10.8% of the recommendations (191 of 1,762) were based on well-conducted RCT and meta-analyses. Hazlehurst JM, Armstrong MJ, Sherlock M, et al. A comparative quality assessment of evidence-based clinical guidelines in endocrinology. *Clin Endocrinol (Oxf)*. 2013;78(2):183-90. See Table 2. Note that this study's use of the terms high, moderate, and low differs from GRADE's.

initial declaration as an example of a clinical practice guideline, written by a professional organization other than the Endocrine Society or WPATH, on a topic other than gender-affirming medical care, whose recommendations are largely based on low- and very low-quality evidence. The purposes of gender-affirming medical care and cardiopulmonary resuscitation are irrelevant to the level of evidence that supports these medical treatments.

24. Several of the Defendants' experts cite comments made by Gordon Guyatt regarding the Endocrine Society's and WPATH's clinical practice guidelines.[33] These comments appear in a features article[34] written by an independent journalist[35] rather than in a peer reviewed article written by Dr. Guyatt himself. One of the potential criticisms is that the Endocrine Society's clinical practice guideline makes strong recommendations based on low- or very low-quality evidence. The GRADE approach does not, however, preclude this from being done and identifies 5 situations in which it is appropriate.[36] The Defendants' experts have not shown that these criteria do not apply to the Endocrine Society's guideline where such strong recommendations were made. They instead seem to categorically dismiss this guideline based on allegations about its methods or results. If applied consistently, these criticisms would also apply to other clinical practice guidelines that are unrelated to gender dysphoria. Table 1 (Exhibit B) of my initial declaration shows that 26 (20%) of the American Heart Association's 130 recommendations in its Guideline for Pediatric Basic and Advanced Life Support are Strong

[33] Cantor 92, 102 and Laidlaw 197.
[34] Block J. Gender dysphoria in young people is rising-and so is professional disagreement. *BMJ*. 2023;380:382.
[35] Jennifer Block. Bio. Accessed June 30, 2023. Available at http://jenniferblock.com/bio/.
[36] Andrews JC, Schunemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66(7):726-735.

recommendations based on Limited Data.[37]

Disclaimers

25. The Response and the Defendants' experts note disclaimers that appear in the Endocrine Society's and WPATH's clinical practice guidelines.[38] The disclaimers in the guidelines emphasize that clinicians must use their judgment in applying the guideline's recommendations to individual patients. When the organizations assert that the guidelines do not establish a "standard of care," they are using this term in the technical legal sense used in malpractice litigation,[39] not in the colloquial sense of an established or recommended practice.

EUROPEAN STATEMENTS

26. The Response and the Defendants' experts reference the reports and decisions of European organizations and agencies.[40] Most importantly, no European country has banned gender-affirming medical care as has Oklahoma. The experts' appeals to this material do not undermine the Endocrine Society's and WPATH's clinical practice guidelines for several reasons including (i) the sources are frequently not available in official English translation, (ii) the experts misrepresent or incompletely report this material, and (iii) they hold this material to a

[37] Topjian AA, Raymond TT, Atkins D, et al. Part 4: Pediatric basic and advanced life support: 2020 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. Circulation. 2020;142(16_suppl_2):S469-S523. These clinical practice guidelines use different terminology than the GRADE approach for describing the quality of the evidence and the strength of recommendations. Limited Data is the 4th of 5 levels of evidence that includes "randomized or nonrandomized observational or registry studies with limitations of design or execution," "meta-analyses of such studies," and "physiological or mechanistic studies in human subjects."

[38] Response 4, 25, Cantor 93, 255, and Laidlaw 191.

[39] Cooke BK, Worsham E, Reisfield GM. The elusive standard of care. *J Am Acad Psychiatry Law*. 2017;45(3):358-364.

[40] Response 2, 12-14, 22-26, Cantor 15-34, 168-172, 298, and Laidlaw 234-240.

different standard.[41]

27. No European country has banned gender affirming medical care as has Oklahoma. The only categorical prohibition of a form of gender-affirming medical care appears to be the Finnish Council for Choices in Health Care's statement, "Surgical treatments are not part of the treatment methods for dysphoria caused by gender-related conflicts in minors." [42] Pubertal suppression and gender affirming hormone treatment are nonetheless permitted for minors in Finland.

28. Oklahoma appears to not only ban gender-affirming medical care, but also the research on gender-affirming medical care for which the Defendants' experts and these European countries call. The ban unjustifiably precludes research in Oklahoma to improve the care of individuals with gender-dysphoria, and unethically suggests that this research's risks should be borne by residents of other states and/or countries and the results then utilized by the residents of Oklahoma.

29. Much of the material on which the Defendants' experts rely is not available in official English translations. Dr. Cantor, for example, references two Finnish documents, Pasternack 2019 (22) and COHERE Recommendation 2020 (24), quoting from the latter. These documents are in Finnish and official English translations, even of an executive summary, are

[41] Dr. Cantor erroneously asserts, "the plaintiffs' experts have excluded all mention of the international reversals of policy (37)." I, in fact, discussed these policies in my initial declaration (57-58).

[42] Palveluvalikoima. Summary: Medical treatment methods for dysphoria associated with variations in gender identity in minors – recommendations. June 16, 2020. Accessed June 29, 2023. Available at https://palveluvalikoima.fi/documents/1237350/22895008/Summary_minors_en+(1).pdf/fa2054c5-8c35-8492-59d6-b3de1c00de49/Summary_minors_en+(1).pdf?t=1631773838474.

not available.[43] Dr. Cantor's Curriculum Vita (Appendix 1) does not indicate that he has reading competency in Finnish.[44] There are sound reasons to believe Google Translate is unreliable to translate medical documents.[45] Other documents have broken links[46] or their original sources are not specified.[47] It, therefore, is difficult to evaluate the Defendants' experts' claims and one must question how they are able to make them in the first place.

30. With respect to the experts' characterization of these materials, they are frequently inaccurate or incomplete. Dr. Cantor, for example, asserts "These range from medical advisories to outright bans on the medical transition of minor (16)." As described above, no European county has banned the medical transition of minors. In addition, Dr. Laidlaw

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[43] Pasternack I, Söderström I, Saijonkari M, Mäkelä M. Lääketieteelliset menetelmät sukupuolivariaatioihin liittyvän dysforian hoidossa. Systemaattinen katsaus. May 15, 2019. Accessed June 29, 2023. Available at https://palveluvalikoima.fi/documents/1237350/22895008/Valmistelumuistion+Liite+1.+Kirjallisuuskatsaus.pdf/5ad0f362-8735-35cd-3e53-3d17a010f2b6/Valmistelumuistion+Liite+1.+Kirjallisuuskatsaus.pdf?t=1592317703000; Palveluvalikoima. Palveluvalikoimaneuvoston suositis: Alaikäisten sukupuoli-identiteetin variaatioihin liittyvän dysforian lääketieteelliset hoitomenetelmät. Accessed May 21, 2023. Available at https://palveluvalikoima.fi/documents/1237350/22895008/Alaik%C3%A4iset_suositus.pdf/c987a74c-dfac-d82f-2142-684f8ddead64/Alaik%C3%A4iset_suositus.pdf?t=1592317701000.

[44] Contrast Dr. Laidlaw's Curriculum Vita which notes conversational Spanish and French.

[45] Cornelison BR, Al-Mohaish S, Sun Y, Edwards CJ. Accuracy of Google Translate in translating the directions and counseling points for top-selling drugs from English to Arabic, Chinese, and Spanish. *Am J Health Syst Pharm*. 2021;78(22):2053-2058.

[46] The link to Swedish Socialstyrelsen Support 2022 (Cantor 28), https://www.socialstyrelsen.se/globalassets/sharepointdokument/artikelkatalog/kunskapsstod/2022-2-7774.pdf, resulted in a 404, page cannot be found, error when I attempted to access the page on June 29, 2023.

[47] Cantor quotes from "a new policy statement" from the Karolinska Instiute, Karolisnka 2021, but does not provide a source for this policy statement in his references or identify who translated it. See also Ukom 2023. While this document does appear to be available on the internet, it is only available in Norwegian. Ukom. Pasientsikkerhet for barn og unge med kjønnsinkongruens. March 9, 2023. Accessed June 30, 2023. Available at https://ukom.no/rapporter/pasientsikkerhet-for-barn-og-unge-med-kjonnsinkongruens/sammendrag. Dr. Cantor does not provide a copy of or source for his unofficial translation.

emphasizes the closure of the Tavistock and Portman Trust's Gender Identity Development Service (235) without noting its replacement by multiple regional centers.[48]

31. Finally, some of the Defendants' experts emphasize that these countries limit the provision of gender-affirming medical care to research protocols without acknowledging that this research need not be RCT. Dr. Cantor, for example, claims "Dr. Antommaria's other argument against RCTs is his belief that 'A randomized trial is unlikely to enroll enough participants.' That belief is also untenable. Healthcare systems of *entire countries* throughout Europe are limiting *all* medicalized transition to minors to research studies (298, reference omitted, italics in original)." He provides no evidence that these studies will be RCT and in fact some countries have explicitly stated that this will not be the case. For example, the Swedish NBHW states, "To ensure that new knowledge is gathered, the NBHW further deems that treatment with GnRH-analogues and sex hormones for young people should be provided within a research context, which does not necessarily imply the use of randomized controlled trials (RCTs)."[49]

32. None of these reports or statements meets the standards to which the Defendants' experts hold the Endocrine Society's and WPATH's clinical practice guidelines. The NBHW's summary of its December 2022 National Guidelines for the care of children and adolescents with gender dysphoria, for example, does not clearly enumerate its recommendations. Some, but not all, of its recommendations are bulleted and bullets are also used to denote reasons for the

[48] The Cass Review. Independent review of gender identity services for children and young people: Interim report. February 2022. Accessed June 30, 2023. Available at https://cass.independent-review.uk/publications/interim-report/.

[49] Socialstyrelsen. Care of children and adolescents with gender dysphoria: Summary. Accessed June 29, 2023. Available at https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-3-7799.pdf. See also, The Cass Review. Independent review of gender identity services for children and young people: Interim report. February 2020. Recommendation 8, Page 22. Accessed June 29, 2023. Available at https://cass.independent-review.uk/publications/interim-report/.

recommendations. This makes it difficult to identify the recommendations. The quality of the evidence supporting each recommendation and the strength of the recommendation is also not consistently specified. Finally, it does not appear from the summary that a systematic review of the literature was conducted in the formulation of every recommendation.[50] The French National Academy of Medicine's statement is in fact a press release.[51] The Defendants' experts appear to hold to a lower standard the materials that they believe support their position.

33. Finally, it should be noted that the Defendants' experts do not provide a systematic review of all European policies; they selectively reference policies that they believe support their position.

INFORMED CONSENT

Parents

34. The Response and the Defendants' experts inappropriately focus on adolescents', rather than their parents', consent.[52] Except in exceptional circumstances, for example, a minor has been emancipated by the court, the consent of parents or legal guardians is required for gender-affirming medical care of minors.

35. Dr. Thompson asserts that parents should not be able to consent to their minor children's gender-affirming medical care because doing so violates their minor child's right to an open future (8, 27, 88, 120, 136). Although uncited by Dr. Thompson, the concept of a right to

[50] Socialstyrelsen: The National Board of Health and Welfare. Care of children and adolescents with gender dysphoria: Summary of national guidelines. December 2022. Accessed June 30, 2023. Available at https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf.

[51] Académie Nationale De Médecine. Medicine and gender transidentity in children and adolescents. February 25, 2022. Accessed June 30, 2023. Available at https://www.academie-medecine.fr/la-medecine-face-a-la-transidentite-de-genre-chez-les-enfants-et-les-adolescents/?lang=en.

[52] Response 26, Cantor 236, and Thompson 9.

an open future was developed by the legal philosopher Joel Feinberg[53] and the bioethicist Dena Davis.[54] There are substantial problems with this putative right, including the inability to differentiate options and whether they are open or closed, and the impossibility and undesirability of keeping all options open.[55] Delaying gender-affirming medical care, for example, permits the development of secondary sexual characteristics inconsistent with an individual's gender identity that are partially irreversible and may equally foreclose other options in a child's life. Dr. Thompson's claims do not provide an adequate ethical basis for criminalizing gender-affirming medical care for minors.

36. Dr. Thompson's claims also highlight the ban's inconsistent treatment of different medical conditions. The ban permits other medical treatments to which their claims regarding the right to an open future would also apply; the ban permits procedures to treat individuals with medically verifiable differences or disorders of sex development (DSD). Non-emergent medical procedures, to which parents can consent, to treat DSD which have similar long-term ramifications include feminizing genioplasty and gonadectomy.[56] The ban treats different medical conditions inequitably and Defendants' experts' claims highlight the lack of justification for this differential treatment.[57]

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[53] Feinberg, J. The child's right to an open future. In *Whose Child? Children's Rights, Parent Authority, and State Power* ed. Aiken W., LaFollettte, H, 124-153. Totowa, JN: Rowman and Littlefield, 1980.
[54] Davis, DS. Genetic dilemmas and the child's right to an open future. *Rutgers L J.* 1997;28:549-592.
[55] Mills, C. The child's right to an open future? *J Soc Philos.* 2003;34:499-509.
[56] Jesus LE. Feminizing genioplasties: Where are we now? *J Pediatr Urol*. 2018;14(5):407-415; Abaci A, Catli G, Berberoglu M. Gonadal malignancy risk and prophylactic gonadectomy in disorders of sexual development. *J Pediatr Endocrinol Metab*. 2015;28(9-10):1019-1027.
[57] Dr. Cantor misconstrues this argument when he states, "However inadvertently, [the plaintiffs] argue that the ban on medical interventions for minor should be *expanded* to include DSDs (277, italics in original)." Rather than inadvertently arguing that the ban should be expanded to include certain interventions for DSD, I argued that gender-affirming medical care and feminizing

37. The Defendants' experts assert that the risk-benefit ratio of gender-affirming medical care is uniquely unfavorable. Dr. Cantor, for example, states, "It is similarly unreasonable to compare the risk:benefit ratio of infertility resulting from medicalized transition to that imposed by treating childhood cancer (Antommaria ¶52): Medicalized transition has not been shown to be superior to the psychotherapeutic alternatives which lack any health risks, whereas the risk of untreated cancer is death (284)." For many individuals, psychotherapy is insufficient to treat their gender dysphoria and they, therefore, seek and their clinicians recommend gender affirming medical care. The "psychotherapeutic alternatives" do not "lack any health risks." For individuals entering puberty, the psychotherapeutic alternatives, in which no medical care is provided, permit the development of secondary sexual characteristics that exacerbate patients' gender dysphoria and that may not be fully reversable in adulthood. These alternatives also risk being ineffective and individuals' dysphoria persisting. Dr. Cantor himself states, "it cannot be assumed that gender identity is immune to influence such as from psychotherapy. Such is an empirical question, and there has not yet been any such research (199)." Asserting that there are no health risks to delaying gender-affirming medical care disregards the documented severe pain and suffering that many individuals with gender dysphoria experience.

38. Claims that parents and legal guardians are inadequately informed or are coerced

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genitoplasty are similar in relevant respects and should be treated similarly. Both are performed to make an individual's body more consistent with their expressed or anticipated gender identity and feminizing genitoplasty is supported by equal, if not lower, quality evidence than gender-affirming medical care. Jesus LE. Feminizing genioplasties: Where are we now? *J Pediatr Urol*. 2018;14(5):407-415. Dr. Cantor's putative distinctions between physical medical and mental psychiatric disorders, and objective and verifiable and subjective and unverifiable evidence are irrelevant. Although similar, the ban treats them differently; it prohibits gender-affirming medical care and permits feminizing genitoplasty without justification. My conclusion is that, rather than banning both, the state should ban neither.

lack empirical evidence.[58] Even if these claims regarding disclosure and voluntariness were true, and they are not, there are many well-established means to address inadequate informed consent other than banning gender-affirming medical care. Such means include credentialing,[59] licensing,[60] and malpractice litigation.[61]

39. Claims that parents cannot understand the relevant information is also without foundation. Uncertainty does not preclude capacity. Parents can understand, appreciate, and evaluate known risks of uncertain frequency and unknown risks. When parents enrolled their children in clinical trials of COVID-19 vaccines, for example, they understood that the vaccine might not be effective and that there were potentially unknown side-effects. This is in the context of an intervention, a vaccine, that cannot be removed once administered. Even after COVID-19 vaccines were authorized by the FDA for pediatric age groups, there remained uncertainty about side-effects both because the vaccines were tested on relatively small numbers of children and because follow up had been for a limited time. [62] Decisions parents make regarding gender-

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[58] Dr. Thompson asserts that parents do not have the ability to provide fully informed consent because there are no guidelines for fertility preservation for transgender individuals (9). This is a misstatement of the elements of informed consent. Informed consent requires the disclosure of material information. Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. 8th ed. Oxford University Press; 2019. The lack of guideline, however, does not necessarily mean that material information has not been disclosed.

[59] Patel R, Sharma S. Credentialing. *StatPearls*. October 30, 2021. Accessed June 30, 2023. Available at https://www.ncbi.nlm.nih.gov/books/NBK519504/.

[60] Federation of State Medical Boards. About physician discipline. Accessed June 30, 2023. Available at https://www.fsmb.org/u.s.-medical-regulatory-trends-and-actions/guide-to-medical-regulation-in-the-united-states/about-physician-discipline/.

[61] Dobbs D, Hayden P, Bublick E. Liability of health care providers. *Hornbook on Torts*. 2nd ed. West Academic Publishing; 2016.

[62] The FDA issued an Emergency Use Authorization for the Pfizer-BioNTech vaccine for children 5 to 11 years of age based on studies of approximately 4,700 children and examined the risk of contracting COVID-19 7 days after the second dose. See U.S. Food & Drug Administration. FDA authorizes Pfizer-BioNTech COVID-19 vaccine for emergency use in children 5 though 11 years of age. October 29, 2021. Accesses June 30, 2023. Available at https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-

affirming medical care are comparable to other decisions that they make for their children that the Defendants' experts do not appear to challenge.

Minor Patients

40. Dr. Thompson asserts that "children and adolescents who undergo the current regimen of [gender affirming care] do not have the development, intellectual, or emotional maturity to assent to the treatment (9)."[63] While adolescents engage in greater risk taking than adults, this is context dependent. In "cold" contexts, that are less emotionally laden and involve less peer influence, adolescent decision-making capacity is comparable to adults.[64] It should be emphasized that health care providers promote environments which enhance adolescents' decision-making capacity. The difference in context accounts for minors' lack of maturity to make certain decisions.[65]

41. There is evidence that adolescents have adequate decision-making capacity to consent to puberty suppression. Lieke J.J.J. Vrouenraets and colleagues used the treatment version of the MacArthur Competence Assessment Tool to assess the capacity of transgender adolescents, who had completed their diagnostic evaluation and were ready to start puberty suppression, to consent. (Individuals who were not yet Tanner Stage 2 or had serious psychiatric conditions or psychopathology that would interfere with treatment were appropriately not included in this study.) Seventy-three adolescents participated. Their mean age was 14.71 years old, and their ages ranged from 10.63 to 18.34. Sixty-six (89.2%) of the participants were judged

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vaccine-emergency-use-children-5-through-11-years-age#:~:text=Press%20Announcements-,FDA%20Authorizes%20Pfizer%2DBioNTech%20COVID%2D19%20Vaccine%20for%20Emergency%20Use,through%2011%20Years%20of%20Age&text=Today%2C%20the%20U.S.%20Food%20and,through%2011%20years%20of%20age.

[63] See also Laidlaw 257.

[64] Steinberg L. Does recent research on adolescent brain development inform the mature minor doctrine? *J Med Philos*. 2013;38(3):256-267.

[65] Response 26.

to have medical decision-making capacity using this tool.[66]

42. Dr. Thompson calls into question the adequacy of the informed consent process. She, for example, cites one study reporting that only 13.5% of transgender and gender non-conforming adolescents had discussed effects of hormones on fertility with their healthcare providers (9).[67] This contrasts with the Endocrine Society and WPATH guidelines which recommends counseling regarding fertility preservation[68] and studies reporting high rates of disclosure. Diane Chen and colleagues report that all 105 patients in their cohort were provided counseling on the potential impact of hormones on fertility, the availability of fertility preservations options, and the opportunity for further consultation with a fertility specialist.[69] Leena Nahata and colleagues report 98.6% (72 of 73) of patients had fertility counseling documented prior to the initiation of medical treatment.[70] Utilization of fertility preservation does not necessarily reflect the presence or absence of adequate informed consent.

43. Dr. Thompson's argument regarding informed consent, if it were sound, which it is not, does not justify prohibiting gender-affirming medical care until 18 years of age. She

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[66] Vrouenraets L, de Vries ALC, de Vries MC, van der Miesen AIR, Hein IM. Assessing medical decision-making competence in transgender youth. *Pediatrics*. 2021;148(6):e2020049643.
[67] Thompson cites "Cheng P, Pastuszak AW, Myers JB, et al. Fertility concerns of the transgender patient. Transl Androl Urol 2019;8(3):209-218" which is a review article. The original study is Chen D, Matson M, Macapagal K, et al. Attitudes toward fertility and reproductive health among transgender and gender-nonconforming adolescents. *J Adolesc Health*. 2018;63(1):62-68 which is an online survey.
[68] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903; Coleman E, Radix AE, Bouman WP, et al. Standards of care for the health of transgender and gender diverse people, Version 8. *Int J Transgend Health*. 2022;23(Suppl 1):S1-S259.
[69] Chen D, Simons L, Johnson EK, Lockart BA, Finlayson C. Fertility preservation for transgender adolescents. *J Adolesc Health*. 2017;61(1):120-123.
[70] Nahata L, Tishelman AC, Caltabellotta NM, Quinn GP. Low Fertility preservation utilization among transgender youth. *J Adolesc Health*. 2017;61(1):40-44.

asserts that "Because [gender affirming care (GAC)] regime at early pubertal development (Tanner stage 2) will almost certainly result in sterilization (there are no data providing any evidence to the contrary), and because the 'fertility preservation' options for these children and inaccessible, experimental, and speculative, it is my opinion that any notion of informed consent to the risks of GAC at Tanner stage 2 is illusory (11)."[71] Fertility preservation options do become available in Thompson's view at Tanner stage 4. This occurs, on average, at 13 years of age in those assigned female at birth and 14 years of age in those assigned male at birth. Informed consent, based on Thompson's own logic, is available substantially before 18 years of age.

CONCLUSION

44. My review of the Response and the Defendants' experts' reports provides no reason for me to change my opinion that there is no sound medical or ethical basis to criminalize gender-affirming medical care for minors. Doing so puts clinicians in the untenable position of having to either follow state law and knowingly harm their patients or face penalties including imprisonment and loss of their medical licenses.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: July 6, 2023

ARMAND H. MATHENY ANTOMMARIA, MD, PhD

[71] See also Laidlaw 95.